

EXHIBIT 7

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<p style="text-align: right;">Page 5</p> <p>1 Q. You can hold on to that for now.</p> <p>2 A. Okay.</p> <p>3 Q. Have you seen this document before today?</p> <p>4 A. I believe so, yeah, sure.</p> <p>5 Q. Including its list of documents and</p> <p>6 things --</p> <p>7 A. Yep.</p> <p>8 Q. -- to be produced?</p> <p>9 A. Yep.</p> <p>10 Q. Okay. The other commitment we need to</p> <p>11 make to one another -- and I saw this a bit in the</p> <p>12 prior transcript -- is it's important to keep Kara</p> <p>13 from kicking one or both of us that we not talk over</p> <p>14 one another.</p> <p>15 A. Okay.</p> <p>16 Q. Okay?</p> <p>17 A. Yep.</p> <p>18 Q. I'll try real hard to let you complete</p> <p>19 your answer before I move on to the next question.</p> <p>20 If you could do the same to me in reverse.</p> <p>21 A. Thank you. Yep, yep.</p> <p>22 Q. Thanks.</p> <p>23 A. Holler if I screw up. Okay?</p> <p>24 Q. Okay.</p> <p>25 A. Sorry if I --</p>	<p style="text-align: right;">Page 7</p> <p>1 June 1st, 2011 letter from you to Patricia Giordano</p> <p>2 in connection with a plaintiff or a person by the</p> <p>3 name of Gabrielle Bowman; is that correct?</p> <p>4 A. That is correct.</p> <p>5 Q. All right. And Exhibit 5, as numbered, is</p> <p>6 a March 12th, 2013 letter, also to Ms. Giordano, also</p> <p>7 in connection with Gabrielle Bowman.</p> <p>8 If I could get you to confirm that.</p> <p>9 A. Correct.</p> <p>10 Q. All right. And then Exhibit 6 is a report</p> <p>11 that was prepared on your behalf or by you in</p> <p>12 connection with litigation pending in Great Britain;</p> <p>13 is that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And this was the report that was</p> <p>16 addressed, in brief at least, at your last depo and</p> <p>17 was requested by my partner Mr. Strain and provided</p> <p>18 by counsel to us in the interim.</p> <p>19 So I just want to make sure that, to your</p> <p>20 recollection, this is the report that you mentioned</p> <p>21 and that Mr. Strain asked for at your last depo.</p> <p>22 A. My recollection, yes.</p> <p>23 Q. Okay. And then the last of these</p> <p>24 pre-numbered exhibits that we have is two pages of</p> <p>25 time records that I understand from Ms. Brahmhatt</p>
<p style="text-align: right;">Page 6</p> <p>1 Q. There won't be any hollering, but we'll</p> <p>2 work it out.</p> <p>3 All right. So in response to the list of</p> <p>4 documents and things that's included in Exhibit 1,</p> <p>5 you arrived here with your counsel this morning or</p> <p>6 plaintiff's counsel this morning with three different</p> <p>7 documents, four different documents that she handed</p> <p>8 to me. And I'd like to just get those on the record</p> <p>9 so we don't forget that housekeeping matter.</p> <p>10 Because of the way I've numbered them, let</p> <p>11 me say that we've marked as Exhibit 2 to the</p> <p>12 deposition your October 1st report.</p> <p>13 A. No. 2 is my report.</p> <p>14 Q. No. 2 is your report.</p> <p>15 No. 3 is an article entitled Acyclovir in</p> <p>16 Pregnancy Registry. It is dated August 29th, 1988,</p> <p>17 according to the footer and appears to have been</p> <p>18 published in the American Journal of Medicine. It's</p> <p>19 Pages 123 through 128 of Volume 85.</p> <p>20 Would you agree with that?</p> <p>21 A. Yep.</p> <p>22 Q. Okay. So hold on to that one for me, if</p> <p>23 you would.</p> <p>24 A. Okay.</p> <p>25 Q. Exhibit 4, as we've marked it, is a</p>	<p style="text-align: right;">Page 8</p> <p>1 are a supplementation of Exhibit 3 to the last</p> <p>2 deposition.</p> <p>3 Is that an accurate description of those</p> <p>4 two pages?</p> <p>5 A. That is correct.</p> <p>6 Q. Okay. Let's start with the last one. Why</p> <p>7 don't you put Exhibit 7 on top?</p> <p>8 And I don't have a copy of that. So my</p> <p>9 apologies for leaning over on you. I can read upside</p> <p>10 down. That's fine. Tell me what records -- oh,</p> <p>11 thank you very much.</p> <p>12 Ms. Brahmhatt has just provided me with</p> <p>13 an additional copy.</p> <p>14 Exhibit 7, I take it, reflects all the</p> <p>15 additional time you've billed to the Depakote matters</p> <p>16 pending in the U.S. through these sets of counsel</p> <p>17 since your deposition was taken in the Bonner LeJeune</p> <p>18 case on February 21st, 2014?</p> <p>19 A. I haven't billed anybody yet, but that's</p> <p>20 the time sheet.</p> <p>21 Q. Okay. So have you billed anybody for the</p> <p>22 time reflected in Exhibit 3 to the prior depo?</p> <p>23 A. I have not.</p> <p>24 Q. Okay. Do you expect to?</p> <p>25 A. I do.</p>



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1 Q. Okay.

2 A. Let's see. Around four and a half hours,

3 something like that.

4 Q. It looks like it's approaching five.

5 A. Okay.

6 Q. Four hours, 50 minutes.

7 A. Okay. Something like that.

8 Q. And that was doing what?

9 A. I spent the morning reviewing the previous

10 depositions and the things you asked for and my

11 current report and the Riddick report. So I reread

12 those and tried to get up to speed on those.

13 Q. Did you meet with counsel at all?

14 A. I did after 2:30. The 2:40 there, the

15 2:40 to 4:30, I was with counsel.

16 Q. Okay. You made reference again to my list

17 of things to be produced.

18 Did you see anything in this list that

19 would have called for documents that you're aware of

20 the existence of but you were unable to produce them

21 for one reason or another?

22 A. I don't think so.

23 Q. Okay. I'm not suggesting that there would

24 be. Just wanted to make sure.

25 We had added a couple of things. In

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1 particular I'm looking, Doctor, at No. 18.

2 MS. BRAHMBHATT: What exhibit?

3 Q. (By Mr. MacWilliams) No. 18 in here which

4 was any documents you have relating to the events of

5 1982-'83 involving Dr. Robert and your activities or

6 communications relating to those events.

7 Do you have any documents meeting that

8 description?

9 A. I have no documents that I'm aware of that

10 I have. You know, it's been a long time ago; and I

11 certainly don't have them that I'm aware of.

12 Q. Okay. No. 19, which is a new one, is any

13 documents reflecting any contact you've had with

14 Abbott regarding Depakote.

15 Do you have any such documents?

16 A. I don't believe so.

17 Q. If we changed that Abbott to AbbVie, does

18 that change your answer to that question?

19 So Abbott Labs spun off AbbVie

20 January 21st, 2013. So I actually represent two

21 corporate entities, Abbott Laboratories, Inc., and

22 AbbVie. And I didn't put AbbVie in there; but it's

23 in the definition of Abbott earlier in the subpoena,

24 I'm sure, or should have been.

25 A. Yeah.

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1 Q. But I just want to check.

2 Have you had any contact with AbbVie?

3 A. Not that I'm aware of.

4 I mean there may have been some contacts

5 in '82 that I just don't recall. I know they came to

6 my boss's office. But you know about that. We've

7 told you that.

8 If there was any other than that, I am

9 sort of unaware of --

10 Q. Blissfully unaware?

11 A. Huh?

12 Q. Blissfully unaware of those?

13 A. Yeah, I suppose.

14 Q. All right. Well, thanks for going through

15 that list with me.

16 All right. Can we take a look at

17 Exhibit 3?

18 A. Yes.

19 Q. What is it that caused you to bring

20 Exhibit 3 with you to today's deposition?

21 A. I thought in the previous deposition there

22 were questions I was asked repeatedly, I thought,

23 about was it possible to do a pregnancy registry.

24 And I thought this paper showed that it

25 was. In fact, Burroughs Wellcome took on its own to

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1 set up a pregnancy registry in a way of trying to

2 assure the safety of acyclovir or if there were to be

3 a problem to be on top of it.

4 And so I thought as an example about the

5 time -- '84 when they started it. It's about the

6 time of '82 that suggests it could be -- it certainly

7 could be done.

8 Q. Okay.

9 A. And so that's why I put it in.

10 Q. Thank you.

11 You mentioned -- you used the term

12 pregnancy registry, and I was hoping that you could

13 help me get straight the multiple different

14 registries that I've seen in the various transcripts.

15 So let me list them first, and we'll take

16 it from there.

17 A. Okay.

18 Q. I've seen the term pregnancy registry,

19 I've seen the term exposure registry, and I've seen

20 the term birth defects registry.

21 A. Okay.

22 Q. Are there any others that we should add to

23 the list of the registries that you expect to talk

24 about in connection with these cases?

25 A. I suppose that there were -- there are epi

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<p style="text-align: right;">Page 17</p> <p>1 methods like case-control methods. Case control and 2 cohort are terms that come up. I don't know where 3 the -- I mean not -- case control and, yeah, cohort. 4 Q. Okay. So there's other terminology that's 5 related to this subject matter that -- 6 A. Yep. 7 Q. -- we might get into. 8 But, in terms of the types of registries 9 that could or might be put in place to track these 10 kind of issues or help investigate the types of 11 issues we're talking about, pregnancy registry, 12 exposure registry and birth defects registry more or 13 less covers the waterfront? 14 A. I think so. 15 Q. All right. Can you give me working 16 definitions that I should understand for each of 17 these -- and starting with pregnancy registry -- what 18 it means and maybe distinguish between the three? 19 A. Could I start with the birth defects one 20 first? 21 Q. Perfect. That's fine. 22 A. I spent most of my time with birth defects 23 registers. 24 Q. Registries or registers? 25 A. Well, there are many of them around the</p>	<p style="text-align: right;">Page 19</p> <p>1 babies with birth defects. And people do it in 2 different ways. 3 The one I worked on in its early days was 4 a direct result of the thalidomide epidemic. And the 5 raison d'être for the surveillance system was to 6 provide hopefully an early warning system were there 7 to be another drug that caused an epidemic. So 8 that's one of its uses. 9 It also provides the use -- provides the 10 opportunity to do what we call case-control studies. 11 And they can be of various formats, but in short they 12 basically get exposure information after the case has 13 occurred and compare that with a control. 14 And that is the most common way which 15 adverse effects from drugs are discovered whether 16 it's a birth defect issue or whether it's a 17 cardiovascular issue or a -- whatever it is they 18 almost -- not all but almost all from cases in 19 case-control studies. 20 So registries give -- you do two basic 21 things in a registry. One is you count and monitor. 22 Let's say we had 100 birth defects that we count. 23 And we could monitor by month, by year, by quarter. 24 In the registries around the U.S., we had one while I 25 was there for a while that was for multiple sites.</p>
<p style="text-align: right;">Page 18</p> <p>1 country and around the world. So the birth defects 2 registries, you know, I have -- I was -- there was 3 one directly in the unit I was in in Atlanta. 4 Q. Right. 5 A. And we did business with some of the 6 others that occurred around the country later. 7 Q. Okay. I was actually detecting a 8 difference between the word registry and register. 9 Is there a functional difference -- 10 A. Not that I -- 11 Q. -- between those two terms? 12 A. I don't think so, no. 13 Q. Okay. So if we said -- and we've got to 14 make sure we don't talk over each other. 15 A. Yep. Sorry. Thank you. 16 Q. If we said birth defects registry, that 17 would be synonymous with birth defects register for 18 our purposes here today? 19 A. I believe that to be true. 20 Q. Okay. And I got you off track. So I'll 21 let you continue. 22 Tell us about what it means to establish a 23 birth defects registry as compared to these other two 24 terms we're going to talk about. 25 A. So a birth defects registry, you count</p>	<p style="text-align: right;">Page 20</p> <p>1 We could get from births around the country the same 2 thing, so on. 3 And then -- so that's a count of the baby, 4 the baby with a birth defect. And one of its 5 disadvantages is not cerebral palsy or other things. 6 It's just birth defects. Not cancer, not heart 7 attack. Birth defects. But it allows you the 8 opportunity, depending upon how well you can assess 9 the exposure, to look at essentially an infinite 10 number of exposures. 11 And so since there were, you know, 100,000 12 environment of chemicals that presumably haven't been 13 tested and no drug is marketed that's been given to 14 pregnant women and yet pregnant women get -- I mean 15 women of reproductive age get pregnant. It's a 16 reasonable way to try to look at whether drugs would 17 cause a birth defect. 18 So the first obligation was to count and 19 see if it went up, down, sideways. And we did that. 20 And then -- 21 Q. You're saying we did that. 22 You did that in connection with a 23 particular registry you're talking about? 24 A. The one I directed in Atlanta for a while, 25 the Metropolitan Atlanta Congenital Defects Program.</p>

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1 Q. Have you ever expressed to FDA in any
2 memorialized way your view that every drug that's
3 going to be -- going to result in pregnancy exposures
4 should have a registry upon launch?
5 A. I don't have any recollection of doing
6 that, although there's still some generic papers I've
7 written I haven't read -- reread to find out if I did
8 say that once.
9 Q. Okay. When you had this conversation
10 with -- is it Roche about Valium?
11 A. It was Roche, yes.
12 Q. Did you tell them at the time, hey, what
13 are you doing, you need a registry?
14 A. I don't remember. Probably not.
15 Q. Is there a -- if you haven't said it in
16 writing, are you aware of anybody else of similar
17 high reputation to yours having said, hey, we've got
18 to have this?
19 A. Say again.
20 Q. Has anybody else in any published way said
21 it is necessary and appropriate and required --
22 should be required for all drug companies to launch
23 pregnancy registries at the same time they launch
24 products that are going to be prescribed to women of
25 child-bearing age?

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1 A. What I took this Burroughs Wellcome paper
2 to say was that Burroughs Wellcome thought that it
3 was their corporate responsibility to set up such a
4 registry, and they did that. And it seems to me if
5 it was reasonable for Burroughs Wellcome to do that
6 it would be reasonable for other companies that are
7 going to have a product on the market that they know
8 women of reproductive age are going to be taking and
9 therefore pregnancies will occur.
10 Q. Acyclovir is what kind of product, Doctor?
11 A. It's a drug to treat a viral infection, I
12 think.
13 Q. Okay. It's not used for any indication
14 that is -- for which valproate is indicated, correct?
15 In laymen's terms, there's no overlap between
16 acyclovir and Depakote, right?
17 A. You mean as drugs?
18 Q. Yes, sir, what they're prescribed for.
19 A. Might be prescribed to the same woman.
20 Same woman might have two things.
21 That's why I couldn't quite figure out
22 what you're asking.
23 Q. There's no reason why a doctor would be
24 considering I've got this patient with this
25 condition, should I put her on acyclovir or put her

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1 on Depakote? That doesn't happen?
2 A. I think that's a fair statement.
3 Q. Okay. And, again, I'm not smart enough to
4 be tricky. So I'm just trying to get us a common
5 lexicon here.
6 If Burroughs Wellcome did it for
7 acyclovir, how many other products -- do they
8 mention -- I haven't had the opportunity to go over
9 Exhibit 3 to the extent you have.
10 Does it talk about whether they're going
11 to do that in every case?
12 A. I don't remember seeing that; but, again,
13 I went through it pretty fast.
14 Q. How many drugs -- Burroughs Wellcome isn't
15 around anymore in that -- as that name, right? Do
16 you know who they are these days?
17 A. I don't really know frankly.
18 Q. Okay. Me neither.
19 Do you know whether Burroughs Wellcome at
20 the time had a roster of other drugs that were
21 prescribed for women of child-bearing age?
22 A. I don't know.
23 Q. Recognizing that you only looked through
24 this article briefly in the last few days, have you
25 explored whether Burroughs Wellcome or its successor

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1 actually did this same setup for any other drug?
2 A. I haven't looked at that.
3 Q. Are you aware of any -- pardon me while I
4 look to see when this was published.
5 A. I think it's '84. It's '88 but it started
6 in '84.
7 Q. That's what I was going to get at.
8 So the publication is '88. It's referring
9 back to a registry that the inception of which was
10 '84.
11 Are you aware of any published follow-up
12 to this '88 article?
13 A. No.
14 Q. So we don't know sitting here today
15 whether it worked, didn't work, how long it took, how
16 many cases they ever got, that sort of thing?
17 A. It may be known.
18 I frankly just found this this morning.
19 So I didn't follow it up, no.
20 Q. Okay.
21 A. But I thought one of the issues was was it
22 possible to do this in this time frame. And I think
23 this clearly demonstrates it's possible to do it.
24 That's what struck my eye when I saw it. There's no
25 question this could be done and just as, I think,

